**Section 1325.45 Classification of Devices**

a) The Centers for Medicare and Medicaid Services' (CMMS) Common Procedure Coding System (HCPCS) is used as a universal coding database for orthotic, prosthetic, and pedorthic devices. To determine the appropriate level of supervision, the following categorizations are used:

1) "Custom fabricated and fitted device" means an orthosis, prosthesis, or pedorthic device fabricated to original measurements and/or a mold for patient use in accordance with a prescription and that requires substantial clinical and technical judgment in its design and fitting. Licensees or non-licensed caregivers under direct or close supervision of a licensee should provide custom fabricated and fitted devices.

2) "Custom fitted device" means a prefabricated orthosis, prosthesis, or pedorthic device sized and/or modified for patient use in accordance with a prescription, and that requires substantial clinical judgment and substantive alteration for appropriate use. Licensees or non-licensed caregivers under close or indirect supervision of a licensee should provide custom fitted devices. Custom fitted devices are sub-classified as "high complexity" or "low complexity".

A) Custom fitted device (high complexity): A prefabricated orthosis, prosthesis, or pedorthic device sized and/or modified for patient use in accordance with a prescription and that requires substantial clinical judgment (involving high clinical assessment and patient management skills) or substantive alteration (involving medium technical implementation skills) for appropriate use.

B) Custom fitted device (low complexity): A prefabricated orthosis, prosthesis, or pedorthic device sized and/or modified for patient use in accordance with a prescription and that requires substantial clinical judgment (involving medium clinical assessment and patient management skills) or substantive alteration (involving low technical implementation skills) for appropriate use.

3) "Off-the-shelf device" means a prefabricated orthosis, prosthesis or pedorthic device sized and/or modified for patient use in accordance with a prescription and that does not require substantial clinical judgment and substantive alteration for appropriate use. Licensees or non-licensed caregivers under indirect supervision of a licensee may provide off-the-shelf devices.

4) "Over-the-counter device" means a prefabricated, mass-produced device that is prepackaged and requires no professional advice or judgement in either size selection or use, including fabric or elastic supports, corsets, generic insoles, elastic hose. Over-the-counter devices do not require the supervision of a licensee.

b) The Division hereby incorporates by reference the HCPCS Payment Codes, available from the Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore MD 21244, at http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/index.html? redirect=/medhcpcsgeninfo/.

(Source: Amended at 37 Ill. Reg. 4861, effective April 1, 2013)